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| APPLICATION NO.               | F          | ILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|-------------------------------|------------|------------|----------------------|-------------------------|------------------|
| 10/049,429                    | 09/08/2003 |            | Joseph Schlessinger  | 038602-1306             | 3634             |
| 22428                         | 7590       | 09/03/2004 |                      | EXAMINER                |                  |
| FOLEY AN                      | ID LARI    | DNER       | STEADMAN, DAVID J    |                         |                  |
| SUITE 500<br>3000 K STREET NW |            |            |                      | ART UNIT                | PAPER NUMBER     |
| WASHINGTON, DC 20007          |            |            |                      | 1652                    |                  |
|                               |            |            |                      | DATE MAILED: 09/03/2004 | 4                |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.   | Applicant(s)                 |  |  |  |  |
|---|---|------------------------------|--|--|--|--|
| Office Antique Commence   | 10/049,429  | SCHLESSINGER ET AL.          |  |  |  |  |
| Office Action Summary   | Examiner  | Art Unit                     |  |  |  |  |
|   | David J Steadman  | 1652                         |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |   |                              |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                              |  |  |  |  |
| Status  |   |                              |  |  |  |  |
| 1) Responsive to communication(s) filed on  | <u>_</u> .  |                              |  |  |  |  |
| •   | action is non-final.  |                              |  |  |  |  |
|   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. |                              |  |  |  |  |
| Disposition of Claims   |   |                              |  |  |  |  |
| 4) Claim(s) 1-89 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) is/are rejected.  7) Claim(s) is/are objected to.  8) Claim(s) 1-89 are subject to restriction and/or election requirement.  |   |                              |  |  |  |  |
| Application Papers  |   |                              |  |  |  |  |
| <ul> <li>9) The specification is objected to by the Examiner.</li> <li>10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> <li>11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</li> </ul>   |   |                              |  |  |  |  |
| Priority under 35 U.S.C. § 119  |   |                              |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>  |   |                              |  |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 4)  |                              |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date   | _, [7]  | ratent Application (PTO-152) |  |  |  |  |

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## **DETAILED ACTION**

## Status of the Application

- [1] Claims 1-89 are pending in the application.
- [2] Applicants' amendment to the specification, filed October 16, 2002, is acknowledged.
- [3] Receipt of an information disclosure statement, filed March 21, 2002, is acknowledged.
- [4] The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because: Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).
- The specification is objected to as applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph.

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## Lack of Unity

[6] Lack of unity is required under 35 U.S.C. 121 and 372. This application contains the following inventions or goups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

**Group I**, claims 1-12, 17, 69-74, and 76, drawn to the special technical feature of a crystal comprising an extracellular domain of a receptor protein tyrosine kinase (RPTK), including fibroblast growth factor receptor 1, optionally further comprising a ligand bound to the RPTK, wherein the ligand includes fibroblast growth factor 1 (FGF1).

**Group II**, claims 1-8, 13-16, and 69-77, drawn to the special technical feature of a crystal comprising an extracellular domain of an RPTK, including fibroblast growth factor receptor 1 optionally further comprising a ligand bound to the RPTK, wherein the ligand includes fibroblast growth factor 2 (FGF2).

**Group III**, claims 18, 57, and 78-79, drawn to the special technical feature of a three-dimensional representation of the structure of an extracellular domain of an RPTK, optionally further comprising a ligand bound to the RPTK.

**Group IV**, claims 1, 8, and 19, drawn to the special technical feature of a crystal comprising an extracellular domain of an RPTK, including a mutant RPTK and optionally further comprising a ligand bound to the RPTK.

**Group V**, claim 1, 8, and 20, drawn to the special technical feature of a crystal comprising an extracellular domain of an RPTK, optionally further comprising a mutant ligand bound to the RPTK.

**Group VI**, claims 1, 8, 21-27, 69-74, and 76-77, drawn to the special technical feature of a crystal comprising an extracellular domain of a receptor protein tyrosine kinase (RPTK), including fibroblast growth factor receptor 2, optionally further comprising a ligand bound to the RPTK including FGF2.

**Group VII**, claims 28-40, drawn to the special technical feature of a crystal comprising a polypeptide that includes a receptor binding core of a stem cell factor, optionally further comprising a ligand bound to the receptor binding core.

**Group VIII**, claims 41-42, drawn to the special technical feature of a three-dimensional representation of the structure of a polypeptide that includes a receptor binding core of a stem cell factor, optionally further comprising a ligand bound to the receptor binding core.

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**Group IX**, claims 43-48, drawn to the special technical feature of a computer based system for depicting and analyzing a structure comprising an extracellular domain of an RPTK.

**Group X**, claims 49-51, drawn to the special technical feature of a memory that stores information for generating a visual display of a structure comprising an extracellular domain of an RPTK.

**Group XI**, claims 52-53, drawn to the special technical feature of a computer based system for depicting and analyzing a structure that includes a stem cell factor.

**Group XII**, claims 54-56, drawn to the special technical feature of a method of determining a three-dimensional structure of a RPTK extracellular domain of unknown structure.

**Group XIII**, claims 58-65, drawn to the special technical feature of a method of identifying a modulator of RPTK function.

**Group XIV**, claim 66, drawn to the special technical feature of a modulator of RPTK function.

**Group XV**, claim 67, drawn to the special technical feature of a method of diagnosing a disease.

**Group XVI**, claim 68, drawn to the special technical feature of a method of treating a disease.

**Group XVII**, claims 80-89, drawn to the special technical feature of a computer-readable medium.

[7] The technical feature linking Groups I-VI, IX-X, and XII-XVII is a crystal of a polypeptide including an extracellular domain of an RPTK. The technical feature linking Groups VII-VIII and XI is a crystal of a polypeptide including a receptor binding core of a stem cell factor. The inventions listed as Groups I-XVII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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• According to PCT Rule 13.2 unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. The inventions of Groups I-VI, IX-X, and XII-XVII share no special technical feature with the inventions of Groups VII-VIII and XI as there is no shared same or corresponding special technical feature among the claimed inventions.

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- According to PCT Rule 13.2 unity of invention exists only when the shared same or corresponding special technical feature is a contribution over the prior art. The inventions of Groups I-XVII do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of Groups I-II and IV-VI is a crystal of a polypeptide including an extracellular domain of an RPTK, which is shown by Betzel et al. (*Microgravity Sci Technol* 7:242-245; abstract only) to lack novelty or inventive step because the reference of Betzel et al. teaches a crystal of the extracellular ligand binding domain of an EGF receptor and does not make it a contribution over the prior art.
- 37 CFR 1.475 does not provide for the inclusion of multiple methods of use within the main invention. Accordingly, the methods of Groups XII-XIII do not have unity of invention with the crystal of Group I.
- [8] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
- [9] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Friday (alternate Fridays only) from 6:30 am to 4:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 872-9306. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or

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proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.

**Primary Examiner** 

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08-30-04